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October 29, 2021

**Via E-Mail**

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Re: ***In re Valsartan, Losartan, and Irbesartan Liability Litigation,***  
**Case No. 1:19-md-02875-RBK (D.N.J.)**

Dear Defense Executive Committee:

This letter serves as preliminary notice and demand for corrective action by Defendants in the above-referenced MDL,<sup>1</sup> for whom you serve as the Defense Executive Committee and/or Defense

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<sup>1</sup> The Defendants include: Zhejiang Huahai Pharmaceutical Co., Ltd., Huahai U.S., Inc., Princeton Pharmaceutical Inc., Solco Healthcare U.S., Inc., Hetero Labs, Ltd., Hetero Drugs, Ltd., Hetero USA, Inc., Camber Pharmaceuticals, Inc., Mylan Laboratories, Ltd., Mylan N.V., Mylan Pharmaceuticals, Inc., Aurobindo Pharma, Ltd., Aurobindo Pharma USA, Inc., Teva Pharmaceutical Industries, Ltd., Teva Pharmaceuticals USA, Inc., Actavis Pharma, Inc., Actavis, LLC, Torrent Pharmaceuticals, Ltd., Torrent Pharma, Inc., Walgreens Co., CVS Pharmacy, Inc., Walmart

October 29, 2021

Page 2

Liaison Counsel, concerning breaches of express<sup>2</sup> and implied<sup>3</sup> warranties (including but not limited to U.C.C. § 2-607(3)(a)), as well as violations of state consumer protection statutes,<sup>4</sup> in

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Stores, Inc., Rite-Aid Corporation, Express Scripts, Inc., The Kroger Co., OptumRx, Albertson's LLC, Humana Pharmacy, Inc., Cardinal Health, Inc., McKesson Corporation, and AmerisourceBergen Corporation.

<sup>2</sup> This includes or may include common law express warranty doctrine under the laws of the fifty states, the District of Columbia, and Puerto Rico, as well as the codification of state express warranty law including: Ala. Code § 7-2-313; Alaska Stat. § 45.02.313; Ariz. Rev. Stat. Ann. § 47-2313; Ark. Code Ann. § 4-2-313; Cal. Com. Code § 2313; Colo. Rev. Stat. § 4-2-313; Conn. Gen. Stat. Ann. § 42a-2-313; 6 Del. Code. § 2-313; D.C. Code. § 28:2-313; Fla. Stat. Ann. § 672.313; Ga. Code Ann. § 11-2-313; Haw. Rev. Stat. § 490:2-313; Idaho Code § 28-2-313; 810 Ill. Comp. Stat. Ann. 5/2-313; Ind. Code Ann. § 26-1-2-313; Kan. Stat. Ann. § 84-2-313; Ky. Rev. Stat. Ann. § 355.2-313; 11 Me. Rev. Stat. Ann. § 2-313; Md. Code Ann. § 2-313; Mass. Gen. Law Ch. 106 § 2-313; Mich. Comp. Laws Ann. § 440.2313; Minn. Stat. Ann. § 336.2-313; Miss. Code Ann. § 75-2-313; Mo. Rev. Stat. § 400.2-313; Mont. Code Ann. § 30-2-313; Nev. Rev. Stat. U.C.C. § 104.2313; N.H. Rev. Ann. § 382-A:2-313; N.J. Stat. Ann. § 12A:2-313; N.M. Stat. Ann. § 55-2-313; N.Y. U.C.C. Law § 2-313; N.C. Gen. Stat. Ann. § 25-2-313; N.D. Stat. § 41-02-313; Ohio Rev. Code Ann. § 1302.26; Okla. Stat. tit. 12A § 2-313; Or. Rev. Stat. § 72.3130; 13 Pa. C.S. § 2313; P.R. Laws. Ann. Tit. 31, § 3841, et seq.; R.I. Gen. Laws § 6A-2-313; S.C. Code Ann. § 36-2-313; S.D. Stat. § 57A-2-313; Tenn. Code Ann. § 47-2-313; Tex. Bus. & Com. Code Ann. § 2-313; Utah Code Ann. § 70A-2-313; Va. Code § 8.2-313; Vt. Stat. Ann. 9A § 2-313; W. Va. Code § 46-2-313; Wash. Rev. Code § 62A 2-313; Wis. Stat. Ann. § 402.313 and Wyo. Stat. § 34.1-2-313.

<sup>3</sup> This includes or may include common law implied warranty doctrine under the laws of the fifty states, the District of Columbia, and Puerto Rico, as well as the codification of state implied warranty law including: Ala. Code § 7-2-314; Alaska Stat. § 45.02.314; Ariz. Rev. Stat. Ann. § 47-2314; Ark. Code Ann. § 4-2-314; Cal. Com. Code § 2314; Colo. Rev. Stat. § 4-2-314; Conn. Gen. Stat. Ann. § 42a-2-314; 6 Del. Code. § 2-314; D.C. Code. § 28:2-314; Fla. Stat. Ann. § 672.314; Ga. Code Ann. § 11-2-314; Haw. Rev. Stat. § 490:2-314; Idaho Code § 28-2-314; 810 Ill. Comp. Stat. Ann. 5/2-314; Kan. Stat. Ann. § 84-2-314; Ky. Rev. Stat. Ann. § 355.2-314; 11 Me. Rev. Stat. Ann. § 2-314; Md. Code Ann. § 2-314; Mass. Gen. Law Ch. 106 § 2-314; Mich. Comp. Laws Ann. § 440.2314; Minn. Stat. Ann. § 336.2-314; Miss. Code Ann. § 75-2-314; Mo. Rev. Stat. § 400.2-314; Mont. Code Ann. § 30-2-314; Nev. Rev. Stat. U.C.C. § 104.2314; N.H. Rev. Ann. § 382-A:2-314; N.J. Stat. Ann. § 12A:2-314; N.M. Stat. Ann. § 55-2-314; N.Y. U.C.C. Law § 2-314; N.C. Gen. Stat. Ann. § 25-2-314; N.D. Stat. § 41-02-314; Ohio Rev. Code Ann. § 1302.27; Okla. Stat. tit. 12A § 2-314; Or. Rev. Stat. § 72.3140; 13 Pa. C.S. § 2314; P.R. Laws. Ann. Tit. 31, § 3841, et seq.; R.I. Gen. Laws § 6A-2-314; S.C. Code Ann. § 36-2-314; S.D. Stat. § 57A-2-314; Tenn. Code Ann. § 47-2-314; Tex. Bus. & Com. Code Ann. § 2-314; Utah Code Ann. § 70A-2-314; Va. Code § 8.2-314; Vt. Stat. Ann. 9A § 2-314; W. Va. Code § 46-2-314; Wash. Rev. Code § 62A 2-314; and Wyo. Stat. § 34.1-2-314.

<sup>4</sup> This includes or may include: Ala. Code § 8-19-1, et seq.; Alaska Stat. § 45.50.471, et seq.; Arizona Rev. Stat. § 44-1522, et seq.; Ark. Code § 4-88-101, et seq.; Cal. Bus. Prof. Code § 17200, et seq.; Cal. Civ. Code §§ 1750, et seq.; Cal. Bus. & Prof. Code §§ 17500, et seq.; Colo. Rev. Stat. § 6-1-105, et seq.; Conn. Gen. Stat. § 42-110b, et seq.; 6 Del. Code § 2511, et seq.; D.C. Code § 28-3901, et seq.; Fla. Stat. § 501.201, et seq.; Ga. State 10-1-392, et seq.; Haw. Rev. Stat. § 480, et seq.; Idaho Code § 48-601, et seq.; 815 ILCS 505/1, et seq.; Ind. Code Ann. § 24-5-0.5.1, et seq.; Iowa Code Ann. § 714H, et seq.; Kan. Stat. § 50-623, et seq.; Ky. Rev. Stat. § 367.110, et seq.; La. Rev. Stat. § 51:1401, et seq. and alternatively La. Rev. Stat. Ann. § 9:2800.51, et seq.; 5 Me. Rev. Stat. § 207, et seq.; Md. Com. Law Code § 13-101, et seq.; Mass. Gen. L. Ch. 93A, et seq.; Mich. Stat. § 445.901, et seq.; Minn. Stat. § 325F.67, et seq.; Miss. Code Ann. § 75-24-1, et seq.; Vernon's Mo. Rev. Stat. § 407.0 10, et seq.; Mont. Code § 30-14-101, et seq.; Neb. Rev. Stat. § 59-1601, et seq.; Nev. Rev. Stat. § 598.0903, et seq.; N.H. Rev. Stat. § 358-A:1, et seq.; N.J. Stat. Ann. § 56:8-1, et seq.; N.M. Stat. Ann. § 57-12-1, et seq.; N.Y. Gen. Bus. Law § 349, et seq.; N.Y. Gen. Bus. Law § 350, et seq.; N.C. Gen. Stat. § 75-1.1, et seq.; N.D. Cent. Code § 51-15-01, et seq.; Ohio Rev. Stat. § 1345.01, et seq.; Okla. Stat. tit. 15 § 751, et seq.; Or. Rev. Stat. § 646.605, et seq.; 73 Pa. Stat. § 201-1, et seq.; R.I. Gen. Laws § 6-13.1-1, et seq.; S.C. Code Laws § 39-5-10, et seq.; S.D. Code Laws § 37-24-1, et seq.; Tenn. Code § 47-18-101, et seq.; Tex. Bus. & Com. Code § 17.41, et seq.; Utah Code Ann. § 13-11-1, et seq.; Vt. Stat. Ann. Tit. 9, § 2451, et seq.; Va. Code § 59.1-196, et seq.; Wash. Rev. Code § 19.86.010, et seq.; W. Va. Code § 46A-6-101, et seq.; Wis. Stat. § 100.20, et seq.; Wyo. Stat. § 40-12-100, et seq.; and 23 L.P.R.A. § 1001, et seq.

October 29, 2021

Page 3

connection with all plaintiffs pursuing individual and class remedies for personal injuries, economic loss, and medical monitoring in the above-referenced MDL arising out of purchases and/or use of valsartan-containing drugs manufactured, distributed, and/or sold by Defendants.<sup>5</sup> Plaintiffs anticipate filing amended complaints pursuant to the Special Master Order No. 46, which may allege claims under all or some of the states' express warranty laws, implied warranty laws, and consumer protection laws referenced *supra* footnotes 2-4. This letter constitutes notice prior to the filing of those anticipated complaints.

Plaintiffs in the above-referenced MDL were prescribed and were dispensed valsartan-containing medication manufactured by one or more Manufacturer Defendants; that may have been distributed by one or more Wholesaler Defendants; and that may have been dispensed by one or more Retail Pharmacy Defendants. Plaintiffs received valsartan-containing drugs that were contaminated with nitrosamines, including n-nitrosodimethylamine (NDMA) and nitrosodiethylamine (NDEA). Nitrosamines are carcinogenic substances that should not be present in valsartan. On July 13, 2018, the U.S. Food & Drug Administration announced the first of a series of voluntary recalls of valsartan-containing medications, including those manufactured and distributed by Defendants. The recalls were due to the presence of NDMA and NDEA in the recalled products. This defect rendered the products unusable and unfit for human consumption. In short, the valsartan-containing medications that Plaintiffs purchased were worthless as they were contaminated, thereby rendering them unfit for human use. Plaintiffs seeking remedies for personal injuries additionally suffered such injuries as a result of ingesting these valsartan-containing medications, and Plaintiffs seeking medical monitoring are at an elevated risk of developing personal injuries as a result of ingesting these valsartan-containing medications. Defendants each violated express and implied warranties made to Plaintiffs and similarly situated purchasers regarding the quality and safety of the valsartan-containing medications they purchased, *see* U.C.C. §§ 2-313, 2-314, and also were harmed under state consumer protection statutes as a result of Defendants' unfair, deceptive, fraudulent, and/or unconscionable trade practices insofar as they merchanted these valsartan-containing drugs. *See supra* n.4.

We hereby demand, on behalf of Plaintiffs and similarly situated purchasers, that Defendants immediately, (1) cease and desist from continuing to sell contaminated valsartan-containing medications, and take appropriate steps to ensure future valsartan-containing medications sold are not contaminated, (2) make full restitution/recompense to all purchasers of the contaminated valsartan-containing medications of all purchase money obtained from sales thereof, (3) make full restitution/recompense to Plaintiffs who suffered personal injuries as a result of ingesting valsartan-containing medications, and (4) establish a fund or service for screening for

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<sup>5</sup> Plaintiffs include any person to file a short form complaint for personal injuries; Samuel Rivera, Denise Gipson, Samella Jackson, Rick Monchamp, Josephine Bell, Kenneth Berkson, Roland Butler, Sylvia Cotton, Jo Ann Hamel, Anthony Martinez, Marlin Anderson, Marilyn Andre, Sandy Bell, Alphonse Borkowski, Billy Joe Bruner, Gary Burnett, Joseph Cacaccio, James Childs, Samuel Cisneros, Glenda Cooper, Linda Crocker, Miranda Dudley, John Duffy, Lawrence Edwards, Eric Erwin, Georgia Fatigato, Fernando Feijoo and the Estate of Elenora Deutenberg, Leland Gildner, Marzana Glab, Mark Hays, Jennifer Johnson, Charlie Johnston, Dennis Kaplan, Sandra Kelly, Joseph Kessinger, Asha Lamy, James Lawson, Jyona Gail Lee, Veronica Longwell, Flora McGilvery, Mary McLean, Jay Meader, Brittney Means, Ronald Molinaro, Cheryl Mullins, Talsie Neal, Gerald Nelson, Peter O'Brien, Lubertha Powell, Evelyn Rice, Robin Roberts, Larry Semmel, Radhakrishna Shetty, Antoinette Sims, Brian Wineinger, Raleigh Wolfe, Maine Automobile Dealers Association, Inc., MSP Recovery Claims, Series LLC; and all similarly situated persons or entities that are part of any class seeking recovery for economic losses and/or medical monitoring.

October 29, 2021

Page 4

potential personal injuries as a result of ingesting valsartan-containing medications. We also demand that Defendants continue to preserve all documents and other evidence which refer or relate to any of the above-described practices including, but not limited to, the following:

1. All documents concerning the packaging, labeling, and manufacturing process for valsartan-containing medications;
2. All documents concerning the design, development, supply, production, extraction, and/or testing of valsartan-containing medications manufactured and distributed and sold by Defendants
3. All tests of the valsartan-containing medications manufactured and distributed and sold by Defendants;
4. All documents concerning the pricing, advertising, marketing, and/or sale of valsartan-containing medications manufactured and distributed and sold by Defendants;
5. All communications with customers involving complaints or comments concerning the valsartan-containing medications manufactured and distributed and sold by Defendants;
6. All documents concerning communications with any retailer involved in the marketing or sale of valsartan-containing medications manufactured and distributed and sold by Defendants;
7. All documents concerning communications with federal or state regulators; and
8. All documents concerning the total revenue derived from sales of valsartan-containing medication.

If you contend that any statement in this letter is inaccurate in any respect, please provide us with your contentions and supporting documents immediately upon receipt of this letter.

Please contact me right away if you wish to discuss an appropriate way to remedy this matter. If we do not hear from you promptly, we will take that as an indication that you are not interested in doing so.

October 29, 2021

Page 5

Truly Yours,

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*/s/ Ruben Honik*

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*/s/ Daniel Nigh*

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*/s/ Adam Slater*

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*/s/ Conlee S. Whiteley*

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***MDL Plaintiffs' Co-Lead Counsel***

cc: Plaintiffs' Executive Committee